

REMARKS

The Office Action mailed September 10, 2010, has been carefully studied. The claims in the application remain as claims 14, 17-21, 24-29, 32-34, 36-38 and 41, and these claims define patentable subject matter and should be allowed. Favorable reconsideration and allowance are again respectfully requested.

Amendments have been made above in consideration of commentary made in the Official Action of September 10, 2010. Of particular note is the commentary by the examiner on page 7, second paragraph, where the examiner stated that the effects shown in Tables 1 and 2 are not recited in the rejected claims, whereby arguments in the last reply are not persuasive. Each of the independent claims has now been amended to recite the unobvious effects set forth in Tables 1 and 2 of Applicants' specification.

Claim 36 has been objected to for using the introductory language "In a hemostatic... ." This objection is respectfully traversed.

The introductory language used by Applicants is the traditional and usual language often used in a Jepson-style claim. Nevertheless, the suggestion made by the examiner has been adopted, and Applicants request withdrawal of the objection.

Claims 20 and 27 have been rejected under the second paragraph of §112, which claims are improperly dependent.

The dependency of claims 20 and 27 has now been corrected. Similarly, the dependence of claim 34 has also been corrected.

Withdrawal of the objection is respectfully requested.

Claims 14, 17-21, 24-29, 32-34, 36-38 and 41 have been rejected as obvious under §103 from Sugitachi in view Greenawalt and further in view of Gunze JP 63-09504 which is said to be the "same as" the English translation of JP 1993-018527. This rejection is respectfully traversed for reasons of record, respectfully repeated by reference, and for the additional reasons set forth below.

According to the rejection, Sugitachi teaches an absorbable material such as polyglycolic acid comprising thrombin, and a process making same by dipping the material in a saline solution of thrombin, followed lyophilization. As previously noted, the absorbable braided suture of polyglycolic acid was dipped in an aqueous solution of Factor XIII. The question under §103 is what does Sugitachi teach the person of ordinary skill in the art.

It is clear that the gist of the invention of Sugitachi resides in the **fixation of Factor XIII** to a wound healing material, as noted from col. 1, lines 32-45, and col. 3, lines 8-20. The abstract of Sugitachi thus states, very simply, that Sugitachi is directed to:

A wound healing material having blood coagulation Factor XIII fixed thereto. This material promotes the formation of stabilized fibrin at a wound site....

According to Sugitachi, thrombin is preferably fixed together with Factor XIII “because it further promotes the formation of non-stabilized fibrin at a wound site.” (Col. 3, lines 20-23).

The wound healing material according to Sugitachi may react with blood from patients to thereby attain hemostasis. In Sugitachi, the idea is to increase the amount of Factor XIII beyond that normally present in serum so as to provide rapid and potent cross-linking of fibrinogen under non-physiological conditions. This is the gist of what Sugitachi is teaching those skilled in the art.

Thrombin is used to promote the reaction by activating Factor XIII for fixation, thrombin being an enzyme and Factor XIII being a substrate for the enzyme. As such, thrombin according to Sugitachi is used merely as an agent for assisting the activity of Factor XIII, and the object in Sugitachi is therefore quite different from the present invention where thrombin is among the main elements.

Applicants are not arguing in this respect about what Sugitachi discloses, but instead against the obviousness of the proposed combination. Thus, Greenawalt is not relevant to the objective of Sugitachi. In other words, bearing in mind the objective of Sugitachi, which objective cannot be properly ignored or brushed aside, there would be no reason to even try to add both thrombin and fibrinogen to the same substrate as set forth by Sugitachi. The proposed combination would not have been obvious at the time the present invention was made, but is now only obvious in retrospect, having read Applicants’ disclosure.

Returning to the disclosure of Sugitachi, Applicants respectfully reiterate their previously stated position as to the non-obviousness of using Applicants' claimed substrate, namely the bioabsorbable synthetic non-woven fabric of polyglycolic acid which is needle-punched and elastic. The person of ordinary skill in the art cannot be expected to try a large number of alternative substrates, none of which is said to be any better than any of the others, in the hope of finding one which possesses improved properties. The law does not require such a large number of comparative tests in the hope of finding a superior product, when there is no hint in the prior art of any advantage of doing so.

With regard to the feature of the claimed fabric being needle punched, it is important for the purpose of endowing the fabric with sufficient flexibility and elasticity to ensure sticking to an area of appropriately any shape, as indicated in claim 36. In the working examples of the present application (see Example 1, page 10, line 17), Neovel was selected for use because it had sufficient flexibility and elasticity as produced by needle punching. Merely because such a fabric has existed previously, or even that it becomes decomposed and absorbed into a living body, is irrelevant to its use as a Sugitachi substrate. The proposed combination would not have been obvious.

Lastly, Applicants have argued the non-obviousness of the present invention, and have pointed to the improved results shown in the present specification. The examiner brushes these improved results aside, stating that they have not been claimed, ignoring the inherent nature of the improved results, whereby it should not be necessary to claim such improved results. Nevertheless, such improved results, namely the effects shown in Tables 1 and 2 of the specification, have now been added to the claims. The prior art provides no reasonable expectation of the effects produced according to the present invention.

Withdrawal of the rejection is in order and is respectfully requested.

Claim 14 has again been provisionally rejected on the basis of obviousness-type double patenting, and the rejection is again respectfully traversed for the reasons of record.

Applicants respectfully reiterate that no claims have been allowed in either application, and therefore there can be no double patenting when the PTO has provided no

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indication of any claims being allowed in the copending Application No. 11/941,779. There can be no **double** patenting when there is no evidence of **single** patenting.

Applicants respectfully request that this rejection be withdrawn.

Favorable reconsideration and allowance are earnestly solicited.

If the Examiner has any questions or suggestions, the Examiner is respectfully requested to contact the undersigned at (202) 628-5197.

Respectfully submitted,

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